REMARKS

Introduction

Claims 1-20 are pending in the application. Claim 20 is new. Claims 1-19 have been amended. Support for the new claim and these amendments can be found throughout the specification, for example, in figure 1, at page 1, page 7 (third paragraph, bridging paragraph to page 8), page 10 (third paragraph), and the claims as filed. These amendments are not believed to introduce new matter.

Rejections under 35 U.S.C. §112

Applicants have amended the claims in a manner that is believed to overcome all the Examiner's rejections under 35 U.S.C. §112. Applicants also wish to note that the term "active form" relates to A1AT without a reduced inhibitory function. In contrast to the active form, the inactive form of A1AT is not capable of inhibiting serine proteases.

This is believed to be a full and complete reply which renders these rejections moot. Accordingly, the rejections under §112 are improper and their withdrawal is respectfully requested.

Rejection under 35 U.S.C. §102

The Examiner has rejected claims 12-19 as allegedly being anticipated by Mattes *et al.* Applicant disagrees, however, solely to expedite prosecution, claim 12 has been amended to recite that " the active form of alpha-1-antitrypsin has a maximum activity of 100%." This claimed feature is shown in figure 1 of the specification which illustrates the results of an SDS-PAGE of A1AT solutions. This electropherogram shows A1AT which corresponds to the band slightly above 50kD when compared to the molecular weight marker in line 1. This band indicates that the A1AT isolated is the same as native plasma and, thus, figure 1 shows that the A1AT containing solution of the claimed invention does not influence the ratio of active/inactive A1AT of native plasma. Therefore, it is apparent to one of skill in the art that the maximal activity of the active form of A1AT is 100%.

In contrast, Mattes *et al.* discloses a method of preparation with A1AT having an activity of at least 120%. This increased activity results from a greater ratio of active to inactive A1AT in the preparation than is present in plasma. See the Abstract of Mattes. Therefore, Mattes *et al.* does not anticipate amended claim 12 or claims 13-19, which depend on claim 12.

The Examiner has also rejected claims 1-5 and 9-11 as allegedly being anticipated by Taniguchi *et al.* Applicants disagree. The claimed method of purifying involves salting the detergents out after treatment (e.g., applying the salt to the elution of the ion-exchange chromatography), as disclosed in Example 1. In contrast, Taniguchi *et al.* applies NaCl solutions for washing the medium prior to use. Thus, Taniguchi *et al.* does not anticipate claims 1-5 and 9-11.

For at least the above reasons, the cited documents do not anticipate the claims. Therefore, the rejection of claims 1-5, 9-11, and 12-19 under 35 U.S.C. §102 is improper and its withdrawal is respectfully requested.

Rejection under 35 U.S.C. §103(a)

Claims 6-8 have been rejected under 35 U.S.C. §103(a) as allegedly being obvious in view of Taniguchi *et al.* and Isaksson *et al.* Applicants disagree. As discussed above, Taniguichi *et al.* does not discuss the "salting out" of the detergents according to the claims. Isaksson *et al.* discloses the removal of detergents using a sodium citrate method but its final product is medically unacceptable because, as seen in Example 4, it comprises 250 ppm Triton X-100 and 35 ppm TNBP. Thus, one of skill in the art would be taught away from using the methods of Isaksson *et al.* in an A1AT purification scheme because of the high levels of residual detergents which render the purified product unacceptable for medical applications. Therefore, as the Examiner notes in the Office Action, because Taniguichi *et al.* does not teach a pasteurization step or a step involving immobilized heparin (e.g., in a gel) it would not have been obvious for one of skill in the art to arrive at the claimed invention, even in view of Isaksson *et al.*

For at least the above reasons, the rejection of claims 6-8 under 103(a) is improper and its withdrawal is respectfully requested.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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